5709. Ake-Ese tablets and Mentho He-Lum ointment. (F.D.C. No. 41564. S. Nos. 6-798 P, 6-798 P.)

QUANTITY: 2,000 boxes of *Ake-Ese tablets* and 228 boxes of *Mentho He-Lum ointment* at Plymouth, Mass., in possession of International Drug Co.

SHIPPED: In 1952, from Norwich, N.Y.

LABEL IN PART: "Blakes * * * Ake-Ese Tablets * * * 30 Tablets * * * Acetanilid ½ Gr. Magnesium Salicylate and Caffeine Flovored with Methyl Salicylate Synthetic" and "Blakes * * * Mentho He-lum Ointment A safe, soothing skin compound."

RESULTS OF INVESTIGATION: The articles were shipped in bulk as described above and subsequently repackaged and labeled by the dealer.

LIBELED: 5-16-58, Dist. Mass.

CHARGE: *Mentho He-lum ointment.* 502(b)(2)—the label of the article, while held for sale, failed to bear an accurate statement of the quantity of contents; and 502(e)(2)—the label of the article failed to bear the common or usual name of each active ingredient of the article.

Ake-Ese tablets. 502(f)(2)—the labeling of the article, while held for sale, failed to bear adequate warnings against unsafe dosage and duration of administration in such manner and form as are necessary for the protection of users since the article contained acetanilid, and the labeling failed to warn that frequent and continued use may cause serious blood disturbances and dependence on the article, and since the article contained salicylates, and its labeling failed to warn that the article should be kept out of reach of children.

DISPOSITION: 7-7-58. Default—destruction.

5710. Gold's Nature Brand tablets. (F.D.C. No. 41843. S. No. 16-207 P.)

QUANTITY: 1,008 100-tablet btls. at Worcester, Mass.

SHIPPED: 5-13-58, from Columbus, Ohio. This was a return shipment.

LABEL IN PART: "Gold's Nature Brand Tablets * * * As a dietary supplement * * * six tablets contain: Tricalcium Phosphate 400 mg. Nux Vomica 6 mg. (not less than 0.07 mg. of Strychnine) Damiana 6 mg. Passion Flower Extract 300 mg. Vitamin B_1 30 mg. Niacinamide 120 mg. Dry Ferrous Sulphate 120 mg. Lecithin 150 mg. Vitamin E 1 I.U."

LIBELED: 5-27-58, Dist. Mass.

CHARGE: 502(f)(1)—the labeling of the article, when shipped, failed to bear adequate directions for use for the purposes for which it was intended.

The article was alleged also to be adulterated under the provisions of the law applicable to foods as reported in notices of judgment on foods, No. 25244.

DISPOSITION: 7-17-58. Default—destruction.

5711. Folix-B tablets with iron. (F.D.C. No. 41846. S. No. 30-499 P.)

QUANTITY: 794 btls. at New York, N.Y.

SHIPPED: In September 1950, from Berkeley, Calif.

LABEL IN PART: (Btl.) "100 Folix-B Tablets With Iron Each containing: Folic acid 3.3 mgs. Thiamin hydrochloride (B_1) 3.0 mgs. Riboflavin (B_2) 6.0 mgs. Niacinamide 30.0 mgs. Pyridoxine hydrochloride (B_6) 100 micrograms Calcium Pantothenate 1.0 mg. Ferrous gluconate 0.3 gm."

RESULTS OF INVESTIGATION: Examination showed that the article contained not more than 34 percent of the labeled amount of vitamin B_1 and not more than 42 percent of the labeled amount of niacinamide.

LIBELED: 6–19–58, S. Dist. N.Y.

CHARGE: 501(c)—the strength of the article, while held for sale, differed from that which it purported and was represented to possess since the article contained less vitamin B_1 and less niacinamide than declared; 502(a)—the label statement "Each containing * * * Thiamin hydrochloride (B_1) 3.0 mgs. * * * Niacinamide 30.0 mgs." was false and misleading as applied to a product containing less than the declared amounts of thiamin hydrochloride and niacinamide, and the label statement "Caution: To be dispensed only by or on the prescription of a physician" was false and misleading as applied to a product that was not restricted to dispensing on a physician's prescription; and 502(f)(1)—the labeling of the article failed to bear adequate directions for use since no dosage statement was given and no indications for use were stated.

DISPOSITION: 7–18–58. Default—destruction.

5712. Creme ointment and suntan lotions. (F.D.C. No. 41902. S. Nos. 1–480/1 P.)

QUANTITY: 2,204 ctns. of *creme ointment*, 643 6-oz. btls., and 242 4-oz. btls., and 27 combination sets of *suntan lotions* at Fort Lauderdale, Fla., in possession of Aloe Creme Laboratories, Inc.

SHIPPED: 1–29–58, from Milwaukee, Wis., by Kolmar Laboratories, Inc.

LABEL IN PART: (Ctn.) "Alo-Creme With Lanolin Ointment * * * Ingredients: Contains 50% or more fresh "gel" from the Aloe Vera leaf, protected in a specially prepared base containing lanolin. Contains no anaesthetic drugs. Distributed by Aloe Creme Laboratories, Inc., Ft. Lauderdale, Florida"; (btl.) "Fashion Tan by Aloe Creme * * * Contains the "gel" of Florida's famous Aloe Vera plant"; (btl.) "After Tan by Aloe Creme * * * contains the "gel" of Florida's famous Aloe Vera Plant in a super rich lanolin base."

ACCOMPANYING LABELING: Leaflets entitled "Sunburn vs. Suntan" and "Aloe-Creme Ointment."

RESULTS OF INVESTIGATION: The leaflets entitled "Aloe-Creme Ointment" and the ctns. for the ointment were prepared locally.

LIBELED: 7–21–58, S. Dist. Fla.

CHARGE: 502(a)—while held for sale, the labeling of the ointment contained false and misleading representation that the article was an adequate and effective treatment for all burns, skin abrasions, cuts, rashes, itching, dermatitis, skin irritations, hemorrhoids, piles, and bed sores; and 502(f)(2)—the ointment was offered for piles and hemorrhoids, and its labeling failed to bear a warning that the article should not be used in case of rectal bleeding.

502(a)—when shipped and while held for sale, the labeling which accompanied the suntan lotions contained false and misleading representations that the articles were an adequate and effective treatment for preventing skin cancer.

DISPOSITION: 11–18–58. Consent—claimed by Aloe Creme Laboratories, Inc., and relabeled.

5713. Medicated cream, inhalant and rubbing oil, and castile soap. (F.D.C. No. 41849. S. Nos. 19–177/9 P.)